

SVP7

Date: 1/13/09

EPA Reg. No.: 83399-6

DP Barcode: D358767

Pest: Flies, lice and mites

Chemical: Dinotefuran (4.95%)
Pyriproxyfen (0.44%)
Permethrin (36.08%)

Shaughnessy
Number: Dinotefuran (044312)
Pyriproxyfen (129032)
Permethrin (109701)

Purpose: Request is to review efficacy data to support label claims for flies,
lice and mites

MRID: 47576002. Young, D (2008) Evaluation of the efficacy of Vectra
3D following topical administration to dogs between 21-55 pounds
of body weight infested with adult Lone Star ticks (*Amblyomma
americanum*); Unpublished study prepared by Young Veterinary
Services, Turlock, CA; Study Project Number SVP/07023; 34 p

47576001. Conti, J (2008) Efficacy Data Support Document.
Project Number: EFFSUPLIT/SVP7/1014. Unpublished study
prepared by Summit Vetpharm; 59 p.

GLP: No

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Joanne S. Edwards
1/13/09
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1/13/09

BACKGROUND:

See previous efficacy review dated May 29, 2008 (under D3528050. Registrant submitted additional efficacy data, mostly published efficacy literature, to support label claims for lice, mites and flies. Also see efficacy review dated April 11, 2008 under D349709.

REVIEW OF DATA

47576002. Evaluation of the efficacy of Vectra 3D following topical administration to dogs between 21-55 pounds of body weight infested with adult Lone Star ticks (*Amblyomma americanum*); Young Veterinary Services, Turlock, CA; Sponsor Summit VetPharm; Study Number SVP 07023; 22 pgs

Study Design:

- Three groups of six dogs each; two of the groups were treated with 3.6 ml of SVP7 (identical to Vectra 3D) at the labeled rate; dogs weighed 21-55 pounds with average weight about 43 pounds; one control group
- Lone Star Infestation: approximately 40 per dog on days -1, 7, 14, 21 and 28.
- Visual counts of live ticks on day 1, 8, 15, 22 and 29
- Comb counts on day 2, 9, 16, 23, and 30.

Reported Results:

Table 1. Mean # Live Ticks Recovered and % Control

Day	Mean # Ticks		% Control
	Control	Treated	
1	10.5	6.8	35.1
2	7.7	7.2	6.2
8	10.3	2	80.8
9	13.7	1.3	90.8
15	11.4	0.2	98.6
16	11.4	0.4	96.2
22	15.5	1.3	91.7
23	14.5	0.1	99.6
29	7.4	0.7	910
30	6.2	0.1	99

The results show greater than 90% control was achieved from day nine to the end of the study (day 30). The topical application of the product at the labeled rate of 3.6 ml for dogs weighing between 21-55 effectively controlled the Lone Star tick for a month. [Note: A Lone Star tick claim already appears on the label.]

47576001. Conti, J (2008) Efficacy Data Support Document. Project Number: EFFSUPLIT/SVP7/1014. Unpublished study prepared by Summit Vetpharm; 59 p.

1. Lice (R. Endris et.al. 2001. Efficacy of a Topical Spot-On Containing 65% Permethrin Against the Dog Louse, *Trichodectes canis* (Mallophaga: Trichodectidae)

Study utilized EXSPOT (65% permethrin, equivalent dose of permethrin as in SVP7). There were 14 dogs (7 treated, 7 control) in the study. One ml was applied as spot-on to dogs weighing less than 15 kg (average weight of 5 dogs was 11.9 pounds) and 2 ml for dogs weighing 15 kg or more (2 dogs – weighed 33 and 49 pounds).

The geometric mean lice per dog (nymphs and adults) for control dogs ranged from 17.0 on day 0 to 25.1 on Day 7 (see Table 2. Lice were eliminated within 7 days after treatment on the treated dogs.

This study (along with previously submitted data on sucking lice under D349709) will support a claim for kill/repel (biting and sucking) lice for up to one month.

2. Flies

(Insecticidal activity and nicotinic acetylcholine receptor binding of dinotefuran and its analogue in the housefly, *Musca domestica*) In laboratory tests on insecticidal activity of dinotefuran and 23 related compounds against the housefly, dinotefuran was found to be less active than imidacloprid and clothianidin by a factor of 10 in molar concentrations.

(Evaluation of 65% Permethrin Spot-On and Deltamethrin-Impregnated Collars for Canine *Leishmania infantum* Infection Prevention) Exospot (65% permethrin) was applied as a spot-on to dogs, with resultant reduced the risk of infection (transmitted by the sand fly) in the treated dogs by 84%.

(Evaluation of a Topical Solution Containing 65% Permethrin Against the Sandfly in Dogs) Exspot was evaluated for repellency and insecticidal activity against the sandfly. Two treated dogs and 2 control dogs were exposed to sandflies. Permethrin was found to have a considerable repellent effect. Insect mortality rates remained high (about 61% during the five weeks after application.

(Repellent Efficacy of a Combination Containing Imidacloprid and Permethrin against Sand Flies (*Phlebotomus papatasi*) on Dogs) Product containing imidacloprid (10% (w/v) -permethrin (50% (w/v) was applied as a spot-on to dogs. Authors stated “...clearly demonstrated the high potential of the imidacloprid/permethrin combination, thus protecting dogs from sandfly bites.”

(Evaluation of 65% Permethrin Spot-On for Prevention of Canine Visceral Leishmaniasis: Effects on Disease Prevalence and the Vectors Diptera:Psychodida) in a Hyperendemic Area) 160 dogs were treated with a 65% permethrin product, three times at monthly intervals. Study authors concluded regular use of 65% permethrin

during months of high risk for leishmaniasis can be useful strategy for reducing the prevalence of the disease in hyperendemic areas.

The composite of published literature are deemed adequate to support a claim for control/repel of sandflies for up to a month.

As stated in previous review, in order to obtain a general fly control claim, three species of flies must be tested (house fly, one species of biting fly (tabanid), and one species of choice).

3. Mites

(Treatment of *Neotrombicula autumnalis* dermatitis in dogs using two topical permethrin-pyriproxyfen combinations) Fourteen dogs naturally infested with mites (with moderate to severe dermatitis) were treated topically with a permethrin-pyriproxyfen combination. The infestations were successfully treated in one to three weeks, with four dogs requiring two applications. The products tested were a pump-spray Duowin Spray (Virbac) and a "line-on" spray (Duowin Spray, Virbac).

These data, in conjunction with previously submitted data see under D352805 for species *Cheyletiella yasguri*) are deemed adequate to support a control claims for killing/repelling mites, excluding those that cause mange, for up to one month.

Additional data are required for mange mites (*Sarcoptes* and *Demodex*) in order to obtain a general mite control claim.

CONCLUSIONS

There is no objection to label claims for lice, mites (excluding mange mites) and sandflies, based on the submitted literature data, and previously submitted data (under D352805 and D349709),

Label Changes Needed:

Revise the terms "biting flies", "non-biting flies" and "flies" to read "sandflies" everywhere the terms appear on the label.

On pg 10, delete the phrase "and the diseases they transmit"

On pg 11, delete the phrase "and prevents further infestation."

On pg 11, delete the sentence "Reduce the risk of vector borne disease..."

On pg 11, delete the sentence "SVP7 helps to reduce..."

On pg 11 delete the sentence "SVP7 rapidly kills flea and may reduce the incidence..."

On pg 11 delete "Prevents fleas on treated dogs..."